Practitioner's Docket No. RO0234US (#90568)

CHAPTER II

Preliminary Classification:
Proposed Class: 206
Subclass: 828

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P., § 601, 7th ed.

TRANSMITTAL LETTER TO THE UNITED STATES ELECTED OFFICE (EO/US)

(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP99/05608	2 August 1999	20 August 1998

TITLE OF INVENTION
METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD

APPLICANT(S)
SCHUMANN, Klaus, SEIBERTZ, Frank and STEINBORN, Peter

Box PCT
Assistant Commissioner for Patents
Washington D.C. 20231

ATTENTION: EO/US

CERTIFICATION UNDER 37 C.F.R. § 1.10*
(Express Mail label number is mandatory.)
(Express Mail certification is optional.)

I hereby certify that this Transmittal Letter and the papers indicated as being transmitted therewith is being deposited with the United States Postal Service on this date Feb. 20, 2001, in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EL148507752US, addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Katherine R. Vieyra
(type or print name of person mailing paper)

Signature of person mailing paper

WARNING: *Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. § 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.*

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).*
*"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.*

NOTE: To avoid abandonment of the application, the applicant shall furnish to the USPTO, not later than 20 months from the priority date: (1) a copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the USPTO; and (2) the basic national fee (see 37 C.F.R. § 1.492(a)). The 30-month time limit may not be extended. 37 C.F.R. § 1.495.

WARNING: *Where the items are those which can be submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (since international application papers are not covered by an ordinary certificate of mailing—See 37 C.F.R. § 1.8.*

NOTE: Documents and fees must be clearly identified as a submission to enter the national state under 35 U.S.C. § 371 otherwise the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.494(f).

I. Applicant herewith submits to the United States Elected Office (EO/US) the following items under 35 U.S.C. § 371:

a. ☒ This express request to immediately begin national examination procedures (35 U.S.C. § 371(f)).

b. ☒ The U.S. National Fee (35 U.S.C. § 371(c)(1)) and other fees (37 C.F.R. § 1.492) as indicated below:

2. Fees

CLAIMS FEE	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
☒	TOTAL CLAIMS	4 -20=	---	× $18.00=	$ ---
	INDEPENDENT CLAIMS	1 -3=	---	× $80.00	---
	MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+$270.00	---
BASIC FEE**	☐ U.S. PTO WAS INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where an international preliminary examination fee as set forth in § 1.482 has been paid on the international application to the U.S. PTO: ☐ and the international preliminary examination report states that the criteria of novelty, inventive step (non-obviousness) and industrial activity, as defined in PCT Article 33(1) to (4) have been satisfied for all the claims presented in the application entering the national stage (37 C.F.R. § 1.492(a)(4)) ..... $96.00 ☐ and the above requirements are not met (37 C.F.R. § 1.492(a)(1)) ..... $670.00 ☒ U.S. PTO WAS NOT INTERNATIONAL PRELIMINARY EXAMINATION AUTHORITY Where no international preliminary examination fee as set forth in § 1.482 has been paid to the U.S. PTO, and payment of an international search fee as set forth in § 1.445(a)(2) to the U.S. PTO: ☐ has been paid (37 C.F.R. § 1.492(a)(2)) ..... $690.00 ☐ has not been paid (37 C.F.R. § 1.492(a)(3)) ..... $970.00 ☒ where a search report on the international application has been prepared by the European Patent Office or the Japanese Patent Office (37 C.F.R. § 1.492(a)(5)) $860.00				$860.00
	Total of above Calculations				= $860.00
SMALL ENTITY	Reduction by 1/2 for filing by small entity, if applicable. Affidavit must be filed also. (note 37 C.F.R. § 1.9, 1.27, 1.28)				– ---
	Subtotal				$860.00
	Total National Fee				$ 860.00
	Fee for recording the enclosed assignment document $40.00 (37 C.F.R. § 1.21(h)). (See item 13 below). See attached "ASSIGNMENT COVER SHEET".				-----
TOTAL	Total Fees enclosed				$ 860.00

*See attached Preliminary Amendment Reducing the Number of Claims.

i. ☒ A Credit Card Payment Form in the amount of $860.00 to cover the above fees is enclosed.

ii. ☐ Please charge Account No. _____ in the amount of $ _____. A duplicate copy of this sheet is enclosed.

***WARNING:** *"To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date: * * * (2) the basic national fee (see § 1.492(a)). The 30-month time limit may not be extended." 37 C.F.R. § 1.495(b).*

WARNING: *If the translation of the international application and/or the oath or declaration have not been submitted by the applicant within thirty (30) months from the priority date, such requirements may be met within a time period set by the Office. 37 C.F.R. § 1.495(b)(2). The payment of the surcharge set forth in § 1.492(e) is required as a condition for accepting the oath or declaration later than thirty (30) months after the priority date. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than thirty (30) months after the priority date. Failure to comply with these requirements will result in abandonment of the application. The provisions of § 1.136 apply to the period which is set. Notice of Jan. 3, 1993, 1147 O.G. 29 to 40.*

3. ☒ A copy of the International application as filed (35 U.S.C. § 371(c)(2)):

NOTE: *Section 1.495 (b) was amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. "The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure the notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date." Notice of Jan. 7, 1993, 1147 O.G. 29 to 40, at 35-36. See item 14c below.*

a. ☒ is transmitted herewith.

b. ☐ is not required, as the application was filed with the United States Receiving Office.

c. ☐ has been transmitted

i. ☐ by the International Bureau.
Date of mailing of the application (from form PCT/1B/308): _____.

ii. ☐ by applicant on _____.
Date

4. ☒ A translation of the International application into the English language (35 U.S.C. § 371(c)(2)):

a. ☒ is transmitted herewith.

b. ☐ is not required as the application was filed in English.

c. ☐ was previously transmitted by applicant on _____.
Date

d. ☐ will follow.

5. ☒ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. § 371(c)(3)):

NOTE: The Notice of January 7, 1993 points out that 37 C.F.R. § 1.495(a) was amended to clarify the existing and continuing practice that PCT Article 19 amendments must be submitted by 30 months from the priority date and this deadline may not be extended. The Notice further advises that: "The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under section 1.121. In many cases, filing an amendment under section 1.121 is preferable since grammatical or idiomatic errors may be corrected." 1147 O.G. 29-40, at 36.

a. ☐ are transmitted herewith.

b. ☐ have been transmitted

i. ☐ by the International Bureau.
Date of mailing of the amendment (from form PCT/1B/308): _____.

ii. ☐ by applicant on (date) _____.
Date

c. ☒ have not been transmitted as

i. ☒ applicant chose not to make amendments under PCT Article 19.
Date of mailing of Search Report (from form PCT/ISA/210.): Nov. 4, 1999.

ii. ☐ the time limit for the submission of amendments has not yet expired. The amendments or a statement that amendments have not been made will be transmitted before the expiration of the time limit under PCT Rule 46.1.

6. ☒ A translation of the amendments to the claims under PCT Article 19 (38 U.S.C. § 371(c)(3)):

a. ☐ is transmitted herewith.

b. ☐ is not required as the amendments were made in the English language.

c. ☒ has not been transmitted for reasons indicated at point 5(c) above.

7. ☒ A copy of the international examination report (PCT/IPEA/409)

☒ is transmitted herewith.

☐ is not required as the application was filed with the United States Receiving Office.

8. ☒ Annex(es) to the international preliminary examination report

a. ☒ is/are transmitted herewith.

b. ☐ is/are not required as the application was filed with the United States Receiving Office.

9. ☒ A translation of the annexes to the international preliminary examination report

a. ☒ is transmitted herewith.

b. ☐ is not required as the annexes are in the English language.

10. ☒ An oath or declaration of the inventor (35 U.S.C. § 371(c)(4)) complying with 35 U.S.C. § 115

a. ☐ was previously submitted by applicant on _____. Date

b. ☐ is submitted herewith, and such oath or declaration

i. ☐ is attached to the application.

ii. ☐ identifies the application and any amendments under PCT Article 19 that were transmitted as stated in points 3(b) or 3(c) and 5(b); and states that they were reviewed by the inventor as required by 37 C.F.R. § 1.70.

c. ☒ will follow.

II. Other document(s) or information included:

11. ☒ An International Search Report (PCT/ISA/210) or Declaration under PCT Article 17(2)(a):

a. ☒ is transmitted herewith.

b. ☐ has been transmitted by the International Bureau. Date of mailing (from form PCT/IB/308): _____.

c. ☐ is not required, as the application was searched by the United States International Searching Authority.

d. ☐ will be transmitted promptly upon request.

e. ☐ has been submitted by applicant on _____. Date

12. ☐ An Information Disclosure Statement under 37 C.F.R. §§ 1.97 and 1.98:

a. ☐ is transmitted herewith.

Also transmitted herewith is/are:

☐ Form PTO-1449 (PTO/SB/08A and 08B).

☐ Copies of citations listed.

b. ☐ will be transmitted within THREE MONTHS of the date of submission of requirements under 35 U.S.C. § 371(c).

c. ☐ was previously submitted by applicant on _____. Date

13. ☐ An assignment document is transmitted herewith for recording.

A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

_____

_____

_____

14. ☒ Additional documents:

a. ☐ Copy of request (PCT/RO/101)

b. ☒ International Publication No. WO 00/10795

i. ☐ Specification, claims and drawing

ii. ☒ Front page only

c. ☒ Preliminary amendment (37 C.F.R. § 1.121)

d. ☒ Other

Notification of the Recording of a Change;
Written Opinion (Dated 19.05.2000)
Response to Written Opinion (dated 18.08.2000)

15. ☒ The above checked items are being transmitted

a. ☒ before 30 months from any claimed priority date.

b. ☐ after 30 months.

16. ☐ Certain requirements under 35 U.S.C. § 371 were previously submitted by the applicant on _____, namely:

AUTHORIZATION TO CHARGE ADDITIONAL FEES

WARNING: *Accurately count claims, especially multiple dependant claims, to avoid unexpected high charges if extra claims are authorized.*

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 08-2441

☒ 37 C.F.R. § 1.492(a)(1), (2), (3), and (4) (filing fees)

WARNING: *Because failure to pay the national fee within 30 months without extension (37 C.F.R. § 1.495(b)(2)) results in abandonment of the application, it would be best to always check the above box.*

☒ 37 C.F.R. § 1.492(b), (c) and (d) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.492(d)), it might be best not to authorize the PTO to charge additional claim fees, except possible when dealing with amendments after final action.

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)–(5) (extension fees pursuant to § 1.136(a).

☐ 37 C.F.R. § 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. § 1.311(b))

NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 C.F.R. § 1.311(b).

NOTE: 37 C.F.R. § 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 C.F.R. § 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

☒ 37 C.F.R. § 1.492(e) and (f) (surcharge fees for filing the declaration and/or filing an English translation of an International Application later than 30 months after the priority date).

SIGNATURE OF PRACTITIONER

Reg. No.: 24,603

D. PETER HOCHBERG, ESQ.

(type or print name of practitioner)

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KRV
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Klaus Schumann, Frank Seibertz and Peter Steinborn

Serial No. :

Filed : (Herewith)

Title : METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD

Attorney File : RO0234US (#90568)

Box PCT
Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Prior to substantive examination of the above-identified application, please amend the application, without prejudice, as follows:

In the Specification:

Page 8, after the last paragraph, insert the following paragraph:

-- The invention has been described with particular emphasis on the preferred embodiments, but variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. --

In the Claims:

1. (Amended) Process for producing hot-seal packs for transdermal therapeutic systems, by transporting, in a predetermined cycle through a sealing unit, two laps, a first lap and a second lap, of continuous pack material composed of two or more layers the first lap having a weldable polymer layer lying against the second lap, and the second lap having a weldable polymer layer

lying against the first lap, and, using a sealing tool which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with pressure and with a temperature of above the melting point of the polymer, for a sealing period, which process comprises:

increasing, while the cycle remains the same, the sealing period by a factor, and

the temperature of the heated sealing heads of the sealing tool being lowered in response to said increase of the sealing period, to reduce the temperature reached within the pack material to a temperature only slightly above the melting point of the polymer layer.

2. (Amended) Process according to Claim 1, further comprising reducing the sealing pressure.

3. (Amended) Process according to Claim 1, further comprising:

advancing, after the predetermined lines on the pack material have first been brought into contact with pressure and with heat, the pack material in the cycle and

bringing said lines on the pack material into contact on a second occasion with pressure and with heat, using the same sealing period.

4. (Amended) Device for performing the process according to Claim 1, comprising a sealing unit with heated sealing tools and a transport device for the pack material, wherein the sealing unit comprises a first and a second cooperating, heated sealing head the second sealing head being arranged or configured on the side of the pack material facing away from the first sealing head, and said sealing heads having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material, with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

5. (New) Process according to Claim 1, wherein said factor is two.

REMARKS

Please note that an IPE Written Opinion (PCT/IPEA/408) was issued May 19, 2000 by the European Patent Office. In response to this, an amendment amending four claims and canceling the fifth claim was submitted to the European Patent Office on August 18, 2000. An International Preliminary Examination Report with transmittal (PCT/IPEA/416 and PCT/IPEA/409) was issued on November 15, 2000, containing an Annex with an amended set of claims 1 through 4 and canceling claim 5. The four amended claims in the Annex are incorporated into this preliminary amendment and amended herein. In addition, one new claim, claim 5, has been added.

The English translation of the specification submitted herewith has headings inserted into it to enhance clarity and conformance with U.S. patent practice, but otherwise is an accurate translation of the original specification. Similarly, the foregoing amendments to the claims, including deleting the reference numbers, are made to place them in conformance with U.S. patent practice and to delete multiple-dependencies, thus reducing the government filing fee. A marked up version of the original amended claims is attached. Accordingly, prosecution on the merits hereof is respectfully requested.

Respectfully submitted,

By: _____
D. Peter Hochberg
Reg. No. 24,603

DPH/ KRV/ Enc. and Attachment: Marked Up Claims

D. Peter Hochberg Co., L.P.A.
The Baker Building - 6th Floor
1940 East 6th Street
Cleveland, Ohio 44114 / (216) 771-3800

EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that the foregoing Preliminary Amendment and any document(s) referred to as attached hereto is being deposited with the United States Postal Service on the date indicated below in an envelope as "Express Mail Post Office to Addressee" service mailing Label Number EL148507752US addressed: Box PCT, Commissioner for Patents, Washington, D.C. 20231.

Date: Feb. 20, 2001

_____
Katherine R. Vieyra

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Klaus Schumann, Frank Seibertz and Peter Steinborn
Serial No.	:	
Filed	:	(Herewith)
Title	:	METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD
Attorney File	:	RO0234US (#90568)

ATTACHMENT TO PRELIMINARY AMENDMENT

MARKED UP CLAIMS SHOWING CHANGES RELATIVE TO THE ORIGINAL VERSION

1. (Amended) Process for producing hot-seal packs[, in particular] for transdermal therapeutic systems, by transporting, in a predetermined cycle through a sealing unit, two laps, a first lap and a second lap, of continuous pack material composed of two or more layers [and in each case] the first lap having a weldable polymer layer lying against the [other] second lap, and the second lap having a weldable polymer layer lying against the first lap, and, using a sealing tool [there] which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with pressure and with a temperature of above the melting point of the polymer, for a sealing period, [characterized in that] which process comprises:

increasing, while the cycle remains the same, [there is an increase in] the sealing period by a factor, [in particular a factor of two,] and

[in that there is a lowering of] the temperature of the heated sealing heads of the sealing tool being lowered in response to said increase of the sealing period, to reduce [(1, 2) such that there is a considerable reduction in] the temperature reached within the pack material [(3, 4), this] to a temperature [then being] only slightly above the melting point of the polymer layer [(8)].

2. (Amended) Process according to Claim 1, [characterized in that] further comprising [there

is also a reduction in] reducing the sealing pressure.

3. (Amended) Process according to Claim 1, [characterized in that,] further comprising advancing, after the predetermined lines on the pack material [(3, 4)] have first been brought into contact with pressure and with heat, the pack material [is advanced] in the cycle and bringing said [these] lines on the pack material [are brought] into contact on [at least] a second occasion [or on further occasions] with pressure and with heat, using the same sealing period.

4. (Amended) Device for performing the process according to [any one of] Claim[s] 1[to 3], comprising a sealing unit with heated sealing tools and a transport device for the pack material, [characterized in that] wherein the sealing unit comprises a first and a second [two] cooperating, heated sealing head[s (1) and (2), said] the second sealing head [(2)] being arranged or configured on the side of the pack material [(3, 4)] facing away from the first sealing head [(1)], and said sealing heads having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material [(3, 4)], with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD

BACKGROUND OF THE INVENTION

Field of the Invention

The invention relates to a process for producing hot-seal packs by welding, in particular for transdermal therapeutic systems (TTSs), and to a tool for carrying out the process.

Description of Prior Art

A known method for producing hot-seal packs for TTSs is to use two laps of packaging laminates, each composed of two or more layers, for example each composed of a layer of paper, of aluminium, and of weldable polymer, such as HDPE (high density polyethylene), Barex (PAN, polyacrylonitrile) or Surlyn (ethylene copolymer), and to bond these laps to one another at predetermined edges and/or lines by means of a heated sealing head while their polymer layers are lying against one another. To this end, the sealing head is pressed onto the laps to be bonded, and these are heated until under this head they exceed the melting point of the polymer layers, which therefore melt and enter into a cohesive bond with one another. This process can also be carried out using heated sealing heads arranged in opposite positions, and these may have the same or different temperatures, in order to accelerate the penetration of heat into the laps lying against one another. For example, the temperatures of each of two sealing heads may be 200°C in the case of packaging laminate with a polymer layer made from Barex with a melting point of 177°C, and the temperature of one sealing head may be 200°C and that of the other may be 70°C in the case of a packaging laminate with a polymer layer made from HDPE with a melting point of 138°C.

In this welding process, since the sealing tool temperature is considerably higher than the melting point, there can be blistering due to evaporation of moisture in the region of the welding zone (Barex), or else there can be excessive pinching of the melted polymer (HDPE) as a result of the necessary but excessive pressure exerted by the sealing tool, and there can also be damage to the pack material, giving defective and incomplete welded seams.

The quality of the welded seams can be improved by lowering the sealing-tool temperatures and the sealing-tool pressure while increasing the sealing period - the residence time of the sealing tool on the pack material. However, this would also imply reducing the cycle rate of the welding machine, and this reduction would cause an undesirable reduction in the output of hot-seal packs.

The object of the invention is to provide a welding process for producing hot-seal packs, in particular for transdermal therapeutic systems, by transporting, in a predetermined cycle through a sealing unit, two laps of continuous pack material composed of two or more layers each having a weldable polymer layer lying against the other lap, and, using a sealing tool which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with pressure and with a temperature of above the melting point of the polymer, for a sealing period, which can improve the quality of the welded seams while the cycle rate of the welding machine remains the same, and to provide a sealing tool for carrying out the process.

This object is achieved in the welding process for producing hot-seal packs, in particular for transdermal therapeutic systems, as described above such that while the cycle remains the same there is an increase in the sealing

period by a factor, in particular a factor of two, and in that there is a lowering of the temperature of the heated sealing heads of the sealing tool such that there is a considerable reduction in the temperature reached within the pack material, this temperature then being only slightly above the melting point of the polymer layer and using a sealing unit with heated sealing tools and a transport device for the pack material, characterized in that the sealing unit comprises two cooperating, heated sealing heads, said second sealing head being arranged or configured on the side of the pack material facing away from the first sealing head, and said sealing heads having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material, with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

Summary of the Invention

The invention envisages an increase in the sealing period, i.e. an increase by a factor deriving from the cycle. For simplicity, the specific case of "doubling" is referred to hereinafter. For the purposes of the invention, the term "doubling" includes increases by other factors.

Description of the Preferred Embodiment

According to the invention, use is made of a known process, by transporting, in a predetermined cycle through a sealing unit, two laps of continuous pack material composed of two or more layers and in each case having a weldable polymer layer lying against the other lap, and, using a sealing tool there which acts upon one lap or a sealing tool which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with

pressure and with a temperature of above the melting point of the polymer, for a sealing period and according to the invention doubling the sealing period without altering the cycle or the output, and by lowering the temperature of the sealing tool so that there is a considerable reduction in the temperature reached within the pack material, this temperature then being only slightly above the melting point of the polymer layer. This very substantially prevents blistering due to evaporation of moisture in the region of the welding zone, and thus considerably improves the quality of the welded seams.

In parallel with this, it is also possible to lower the pressure exerted by the sealing tool, thus avoiding excessive pinching of molten polymer and also avoiding damage to the pack material.

In order to increase the sealing period by a factor, in particular a factor of two, the pack material, after being first brought into contact with pressure and with heat, may be advanced in the cycle, along the predetermined lines, and brought into contact on a second occasion or on further occasions with pressure and with heat, using the same period, during the period in which the subsequent sealed-bag pack is first being brought into contact with pressure and with heat.

To carry out the process, a sealing tool has been developed which has, in succession in the direction of advance, two or more, preferably two, identical contact area structures corresponding to the predetermined weld lines, for placing onto the pack material in order to transfer pressure and heat. The length of one contact area structure in the direction of advance therefore corresponds to the advancement cycle, and therefore, immediately after the advancement cycle - and thus essentially without delay or

cooling - the pack material which has been brought into contact with the first contact area structure by means of the sealing tool is brought into contact on a second occasion or on further occasions with heat and with pressure at the same locations, signifying an increase in the sealing period by a factor, in particular a factor of two.

This sealing tool can therefore work together with a second sealing tool which has the same contact area structure and which has been arranged or designed on that side of the pack material facing away from the first sealing tool.

Brief Description of the Drawings

The invention is illustrated below using an example. The diagrams in the associated drawing are:

FIG. 1 : a side view of a sealing unit,
FIG. 2 : a view from below of a sealing head with a contact area structure,
FIGS 3a and 3b : the method of advance in the process according to the invention, and
FIG. 4 : the cross section through a weld.

FIG. 1 shows a sealing unit which has two sealing heads **1** and **2**, between which are passed two webs **3** and **4** of continuous pack material with, between these and at regular distances and at some distance from the web edges, transdermal therapeutic systems (TTSs) **5** inserted but not secured, for forming sealed-bag packs for these in the cycle. Heating (not shown) has been provided to the sealing heads **1** and **2**, which are pressed against one another during a pause between advances.

The pack material has been formed from a layer made from paper **6**, from an aluminium layer **7**, and from a layer **8** made

from a weldable polymer, the two webs **3** and **4** having been arranged (also FIG. 4) with their polymer layers facing towards the TTSs **5** and towards one another.

FIG. 2 shows that side of the sealing heads **1** and **2** which faces towards the pack material, with the contact areas **9** on each of these. These may have cross-grooving in order to enlarge the surface area. When the two sealing heads **1** and **2** are pushed apart, spaces form between the contact areas and, in a pause between advances, the areas with the TTSs **5** to be packed become positioned in these spaces.

The pack material (**3**, **4**) with the inserted TTSs **5** is transported through the sealing unit within the cycle in order to produce closed sealed-bag packs. During a pause between advances, the two sealing heads **1** and **2** are pressed against one another. The temperatures selected for these depend on the melting point of the polymer used in the pack material, and may also be different, as shown by the examples below.

The contact with heat by way of the sealing heads **1** and **2**, and the transfer of heat into the polymer layers, melt the polymer and produce a cohesive bond between the polymer layers. Since the temperature reached at the polymer layers as a consequence of the temperature at the sealing tools **1** and **2** is only slightly above the melting point of the polymer, the weld is weak and, on occasions, defective. In order to make the weld firm and defect-free, the sealing period is now doubled by bringing the still hot weld areas into contact again with pressure and with the same temperature, for the same period, immediately after the next cycle.

FIGS 3a and 3b illustrate the process. In FIG. 3a the location of the sealed-bag pack I to be produced is in the rear position, based on the direction of advance, between the sealing heads **1** and **2**. The forward sealing edge of these has been shown using dashes. Once the pause between advances has expired, this pause being essentially the same as the sealing period, the pack material (**3**, **4**) is advanced and the sealed-bag pack I to be produced passes into the forward position, where it is again brought into contact with the same temperature and with the same pressure, by way of the same sealing head. The sealed-bag pack 0 has been brought into contact with heat only once, and is rejected. The sealed-bag pack II to be produced follows the first (I) and likewise is brought into contact twice in immediate succession, implying a doubling of the sealing period. The cycle here remains the same.

The two examples below show how the temperatures of the sealing tools **1** and **2** were lowered in comparison with the prior art with only one sealing procedure:

Prior art

Polymer used	Melting point (°C)	Temperature of sealing tools 1 (°C)	2 (°C)	Cycles/h
HDPE	138	197	72	3100
Barex	177	200	200	5800

Process of the invention

Polymer used	Melting point (°C)	Temperature of sealing tools		Cycles/h
		1 (°C)	2 (°C)	
HDPE	138	169	65	3100
Barex	177	200	80	5800

AMENDED CLAIMS

1. Process for producing hot-seal packs, in particular for transdermal therapeutic systems, by transporting, in a predetermined cycle through a sealing unit, two laps of continuous pack material composed of two or more layers and in each case having a weldable polymer layer lying against the other lap, and, using a sealing tool there which acts upon both laps, in order to produce a weld along predetermined lines, bringing the laps into contact with pressure and with a temperature of above the melting point of the polymer, for a sealing period, characterized in that while the cycle remains the same there is an increase in the sealing period by a factor, in particular a factor of two, and in that there is a lowering of the temperature of the heated sealing heads of the sealing tool (1, 2) such that there is a considerable reduction in the temperature reached within the pack material (3, 4), this temperature then being only slightly above the melting point of the polymer layer (8).

2. Process according to Claim 1, characterized in that there is also a reduction in the sealing pressure.

3. Process according to Claim 1, characterized in that, after the predetermined lines on the pack material (3, 4) have first been brought into contact with pressure and with heat, the pack material is advanced in the cycle and these lines on the pack material are brought into contact on a second occasion or on further occasions with pressure and with heat, using the same sealing period.

4. Device for performing the process according to any one of Claims 1 to 3, comprising a sealing unit with heated sealing tools and a transport device for the pack material, characterized in that the sealing unit comprises two cooperating, heated sealing heads (1) and (2), said sealing head (2) being arranged or configured on the side of the pack material (3, 4) facing away from the first sealing head (1), and said sealing heads having, in succession in the direction of advance, two or more identical contact area structures corresponding to the predetermined weld lines for transmitting temperature and pressure to the pack material (3, 4), with the length of one contact area structure in the direction of advance corresponding to the advancement cycle.

A B S T R A C T

The invention relates to a process for producing hot-seal packs, in particular for transdermal therapeutic systems, by welding to one another, at predetermined linear regions and at polymer layers facing towards one another, two laps of continuous pack material composed of two or more layers. To this end, one (or two) sealing tool(s) are used to bring the pack material into contact with pressure and heat. To improve the quality of the welded seams without altering the cycle rate, according to the invention the sealing time is doubled and the temperature of the sealing tool(s) (1, 2) is reduced so that there is a considerable reduction in the temperature reached within the pack material (3, 4), this temperature then being only slightly above the melting point of the polymer used. An example of a sealing tool (1, 2) is given (FIG. 1).

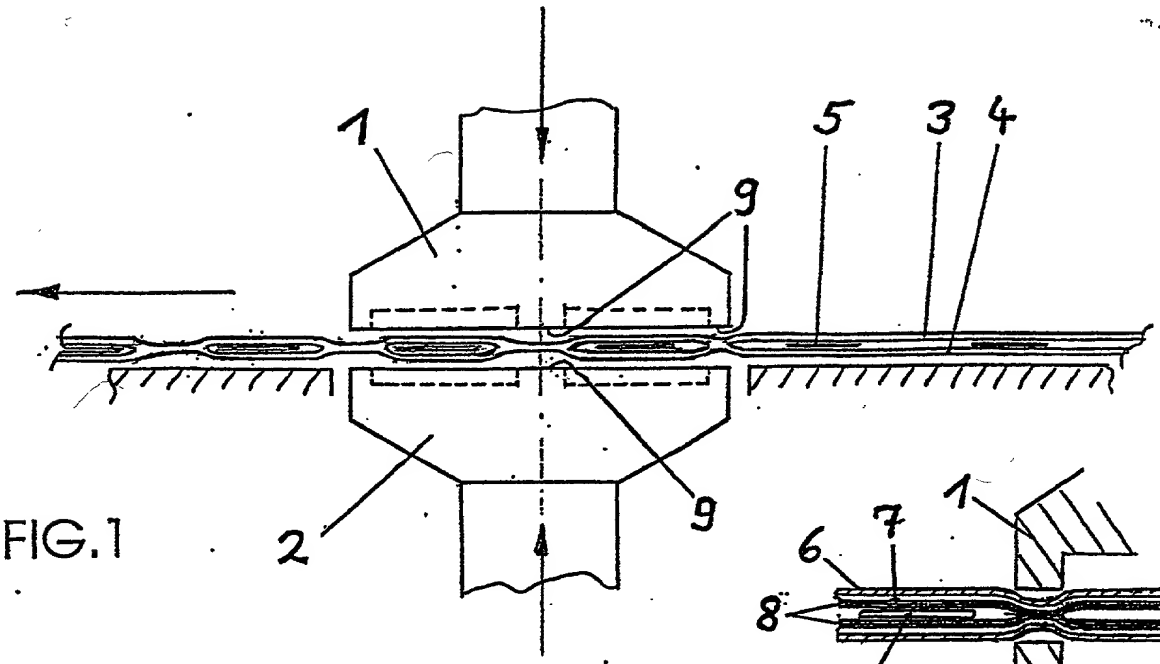


FIG.1

FIG.4

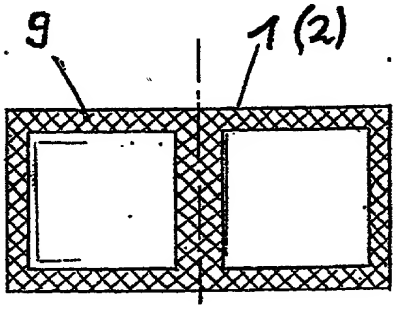


FIG.2

FIG.3a

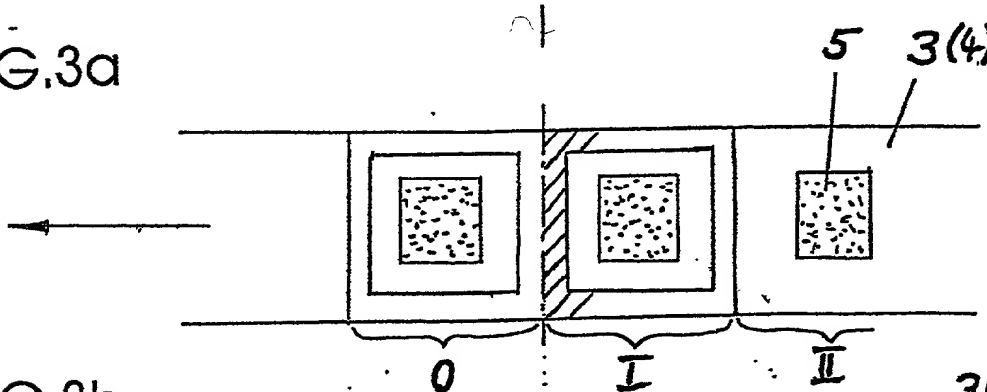
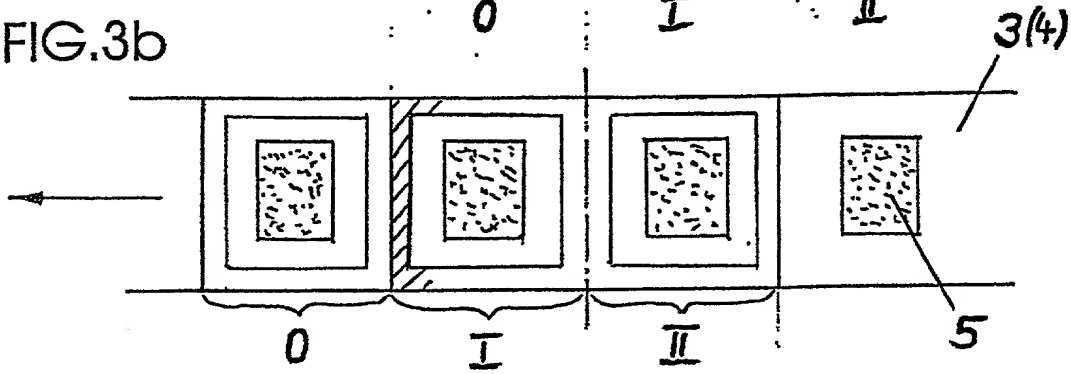


FIG.3b



Attorney Docket No. **RO0234US (#90568)**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: (check one applicable item below)

( ) original
( ) design

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application do not check any of next two items and check appropriate one of last three items.

(X) national stage of PCT
( ) supplemental

NOTE: If one of the following 3 items apply then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR CIP.

( ) divisional
( ) continuation
( ) continuation-in-part (CIP)

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name, I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

METHOD FOR PRODUCING HEAT BONDED PACKAGES AND TOOL FOR IMPLEMENTING SAID METHOD

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b), or (c))

(a) ( ) is attached hereto.
(b) (X) was mailed on **February 20, 2001** as ( ) Serial No. or
(X) Express Mail No. **EL148507752US** , as Serial No. not yet known
and was amended on (if applicable); **and (c) below**

(c) (X) was described and claimed in PCT International Application No. **PCT/EP99/05608** filed on **August 2, 1999** and as amended under PCT Article 19 on (if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations. Sec. 1.56(a).

( ) In compliance with this duty there is attached an information disclosure statement. 37 CFR 1.97.

PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code, Sec. 119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

(d) ( ) no such applications have been filed.
(e) (X) such applications have been filed as follows

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

COUNTRY	APPLICATION NO.	DATE OF FILING (month,day,year)	PRIORITY CLAIMED UNDER 37 USC 119
			( ) YES NO ( )
			( ) YES NO ( )
			( ) YES NO ( )

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

German Appln. 198 37 763.0 filed August 20, 1998
and
PCT Appln. PCT/EP99/05608 filed August 2, 1999

POWER OF ATTORNEY

(3)

As a named inventor, I hereby appoint D. Peter Hochberg, Reg. No. 24,603, Katherine R. Vieyra, Reg. No. 47,155, and William H. Holt, Reg. No. 20,766, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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CHECK PROPER BOX(ES) IF ANY OF THE FOLLOWING ADDED PAGE(S) FORM A PART OF THIS DECLARATION

( ) Signature for fourth and subsequent joint inventors. Number of pages added _____ .

( ) Signature by administrator(trix), executor(trix) or legal representative of deceased or incapacitated inventor. Number of pages added _____ .

( ) Signature for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. Number of pages added _____ .

***

( ) Added pages to combined declaration and power of attorney for

divisional, continuation, or continuation-in-part (CIP) application.

( ) Number of pages added ______ .

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